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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,321	05/30/2001	Volker Lehmann	32226.4	7637

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EXAMINER	
GORDON, BRIAN R	

ART UNIT	PAPER NUMBER
1743	

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DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/870,321	LEHMANN, VOLKER	
	Examiner	Art Unit	
	Brian R. Gordon	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Oath/Declaration

2. The examiner hereby recognizes that the Declaration and Power of Attorney were filed as Paper No. 5 on January 18, 2002; however the document is currently missing from the file. In view of this issue, another copy of the document is hereby requested.

Specification

3. The disclosure is objected to because of the following informalities: The "Significant Figure 5" on the Abstract page should be removed.

Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)),

and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)

(e) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) BRIEF SUMMARY OF THE INVENTION.

(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(h) DETAILED DESCRIPTION OF THE INVENTION.

(i) CLAIM OR CLAIMS (commencing on a separate sheet).

(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Some of the proper section headings are missing from the instant specification. Correction required.

4. The spacing of the lines of the specification is such as to make reading and entry of amendments difficult. New application papers with lines double spaced on good quality paper are required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of aspirating a liquid into a capillary by applying a reduced pressure (that is less than the critical pressure of the liquid) to the liquid and further preventing the aspiration of gas due to the equilibrium reached

between the reduced pressure and the aspirated liquid, does not reasonably provide enablement for a method of aspirating a gas into a capillary by applying a reduced pressure (that is less than the critical of the gas) to the gas and further preventing the aspiration of liquid due to the equilibrium reached between the reduced pressure and the aspirated gas. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The invention of the instant application is directed to a method of aspirating (a minute, minimum amount) a first fluid in a first phase (liquid or gas) into a capillary for subsequent transfer and analysis, wherein a the first fluid is aspirated by applying a reduced pressure (using a pump) to the first fluid that is less than its critical pressure (which is calculated based upon the surface tension of the first fluid) along with the naturally occurring capillary force exerted by the capillary, the applied reduced pressure and capillary force is in the capacity to aspirated the fluid but not in a capacity to aspirate a second fluid in a second phase (liquid or gas, but different from said first fluid), as such only the first fluid is aspirated due to the applied forces.

In some instances the prior art is given such that the pumps used are not capable of applying such small, reduced pressures or variable pressures to prevent the aspiration of a second fluid in particular air/gas that is present in the aspiration environment. In other instances the prior art discloses dispensing and aspiration systems for aspirating fluids of the nanoliter scale. Other prior art disclose methods of aspiration a liquid, wherein air or gas is prevented from entering the capillary after the

aspiration of the liquid by detecting the level or volume of liquid aspirated or detecting a change in pressure within the tube that occurs when air/gas is beginning to be aspirated. The prior art further discloses methods of aspiration involving self-filling, self-limiting, capillaries. The hollow tubular bodies allows for liquids to be drawn into the tubes by capillary attraction.

The state of the art provides evidence for the predictability of such a method as disclosed in the instant application. The predictability of such a method is provided by the guidance provided by those prior art disclosures directed towards the systems of aspiration minute volumes of liquid with negative pressure and those disclosures directed to the aspiration of fluid by self-filling and self limiting capillary devices.

The specification does not provide working examples in which the first fluid aspirated is a gas and the second fluid is liquid. The examiner believes that unless a capillary is vacuum-sealed, air or a gas will occupy the internal space absent of liquid. However upon the action of applying a pressure to aspirate the liquid, the air moves out of the capillary to be replaced by the liquid. There are no examples, explanations, or evidence given to show that the method actually works to aspirate a gas and further prevent a liquid from entering after such aspiration of the gas. Furthermore, it is unclear how such a critical pressure could be calculated for a gas, for it has been understood that gases do not actually have a surface tension, for the gas will expand to occupy the volume of any size container or space. Due to the lack of a working example that provides for an instant in which the first fluid is a gas, the examiner fails to clearly understand how the inventions of the instant application are enabled.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 6, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 1 and 6, the claims are written in a confusing language in which it is difficult to interpret the actual limitations of the inventions. In the apparatus and method of the claims, due to the descriptive phrases, it is unclear if only a first fluid is aspirated or both a first and second fluid is aspirated during the process. For instance one phrase states when the first medium has been taken up fully by the capillary device," (first fluid aspirated and present within capillary) and the phrase "would be taken up into the capillary device" (implies second fluid is aspirated).

The method steps of claim 1 are not given in a clear and precise order for one to clearly perform the intended method claimed. It is suggested that method claim be amended to clearly state each individual step involved in performing the method to derive at applicant's intended result.

In claim one line 3, it is unclear what "the latter" means. If the phrase is meant to refer to a specific limitation, it is suggested that the actual limitation be recited.

Claim 13 recites, "the capillary device is a porous plate". This is inadequate for claim 1 describes the capillary device as having a reduced pressure, being able to contain fluid and coupled to a pump. Furthermore in claim 9, the capillary device is a pipette. It's unclear how the capillary device can be both a pipette and a porous plate.

Claim Rejections - 35 USC § 103

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1, 4, 6, 9, 11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenny US 4,461,328 in view of Kawanabe et al. US 5,452, 619.

Kenny discloses a pipette device comprises one or more pipette tubes. Hydrophobic filter paper secured to each tube limits the upward movement of an aqueous liquid in each tube to provide for a predetermined amount of liquid in each tube. The device can be adapted to be connected to a manifold for alternately applying a vacuum and pressure to the pipette tubes through the filter paper. Alternatively it may have, as an integral part thereof, a manifold for the same purpose.

In operation, the device 2 is positioned with pipette tubes inserted into wells 6 containing an aqueous `liquid` (not shown). A negative pressure is exerted, for example, by `sucking` in on tube 38 which causes the aqueous `liquid` contained in wells 6 to be drawn into pipette tubes 4 until the `liquid` reaches the hydrophobic filter sheet 20 which stops the upward movement of `liquid` in tubes 4. At this juncture, each pipette tube 4 is completely full, containing an exact predetermined amount of `liquid`. The device 2 is then removed from tray 8 and is moved to, for example,

another tray 8 into which it is desired to discharge the liquid contained in pipette tubes 4. Tubes 4 are aligned with the wells into which their contents are to be discharged and a positive pressure, for example, by mouth is applied to tube 38 causing air to pass through the filter sheet 20 and discharge the contained liquid.

It will be understood that the vacuum applied will be consistent with the pore size of the hydrophobic filter sheet so that the pressure differential between the atmospheric pressure and the pressure in the vacuum chamber above the filter sheet will be insufficient to cause the aqueous liquid to enter the filter sheet. This presents no problem since the pressure differential can be small for satisfactory operation compared to the pressure differential necessary to cause the aqueous liquid to enter the filter sheet of a given pore size. Thus an operator's lung suction providing a pressure differential of about 3 p.s.i. is more than adequate for operation, whereas it takes a pressure differential of about 19 p.s.i. to cause liquid to enter the pores of a typical hydrophobic filter sheet having a pore size of 0.2 microns.

As shown in FIGS. 5 and 6, flexible hose 38 may be connected to a conventional prior art vacuum-pressure device 50 which has a two-way solenoid valve 52 which can connect either a pressure line 54 or a vacuum line 56 to flexible hose 38. The position of valve 52 is controlled by a toggle switch 58 which is connected to the solenoid valve 52 by lines 60 and 62 and in turn is connected to a source of power by lines 64 and 66.

Kenny does not disclose that the pipette tubes are dimensioned to provide aspiration of the liquid due to capillary attraction.

Castaneda discloses a process for sampling and diluting a liquid to be diluted utilizing a device comprising a hollow tubular body and a sealed pre-evacuated container. The hollow tubular body includes a self-filling tube for drawing up and capturing by capillary attraction a predetermined volume of a liquid to be diluted.

The hollow tubular body includes a self-filling tube 16 that has an internal diameter selected to draw up by self-filling, a predetermined volume of a liquid to be diluted, and to capture the drawn up liquid. The entire length or less than the entire length of tube 16 may be self-filled to provide the predetermined volume.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device by modifying the pipette tubes of Kenny to have dimensions as taught by self filling device of Castaneda to allow for the application of a reduced pressure provided by the vacuum to reduce the required work of the vacuum and increase the efficiency of the device.

11. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenny in view of Castaneda as applied to claims 1, 4, 6, 9, 11, and 13 above, and further in view of Tajima US 5,895,631.

The modified teachings of Kenny and Castaneda do not teach the employment of an analysis chip within the capillary device.

Tajima discloses a liquid processing method making use of a pipette device which sucks a liquid containing a target high molecular substance from inside of a vessel through a chip detachably set on a sucking port or a discharging port of a liquid sucking/discharging line and transfers this liquid or target high molecular substance to

the next target processing position for the purpose to execute such works as quantifying, separating, taking out, pipetting, clarifying, condensing, and diluting a liquid or a target high molecular substance contained in a liquid.

It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the modified teachings of Kenny by providing the chip analysis pipetting system of Tajima in the modified device in order to perform simultaneous analysis of each sample which provides for time reduction in processing a large number of samples.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lemmo et al., Ingenhoven et al., Osawa et al., El-Hage et al., Inoue et al., Sakai et al., Sakka et al., Kawanabe et al., Rava et al., Flesher, Pelc et al., Woodward, Jacobs et al., Nakano, Komastu, Arai et al., and Matsuyama et al. disclose devices and methods for dispensing fluids to test devices and other containers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

brg

Jill Warden
Supervisory Patent Examiner
Technology Center 1700